REMARKS

Claims 1-64 were originally filed in this Application. By a previous amendment, Claims 59-64 were cancelled. Presently, Claims 1-58 are pending and at issue in this Application. Applicants respectfully note that the Examiner has indicated in the Office Action Summary that Claims 30 and 54-57 are rejected, but has not articulated the grounds on which such claims are rejected. Applicants further note that the Examiner has not taken a position as to the patentability of Claim 58.

A. Information Disclosure Statement

In paragraph 1 of the Office Action, the Examiner objected to the Information Disclosure Statements filed by Applicants in Paper No. 8 and Paper No. 10, for failure to comply with 37 C.F.R. 1.98(a)(2). In a telephone interview, the Examiner informed Applicants' attorney that the objection could be cured by submission of Form PTO-1449 for both of the above Information Disclosure Statements. Accordingly, Applicants transmit herewith a copy of Form PTO-1449 for each of the first two Information Disclosure Statements submitted by Applicants. Applicants thank Dr. Maiorino for her time in conducting the interview with Applicants' attorney.

B. Claim Rejections Under 35 U.S.C. § 102(b)

1. Rejections Over Bloom

In paragraph 1 of the Office Action, the Examiner rejected Claims 1-3, 5, 9-11, 13-18, 24-29, 31-33, 35, 37-38, and 42-52 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,070,761 to Bloom *et al.* ("Bloom"). Applicants respectfully traverse this rejection.

In order for a reference to constitute a §102(b) bar to patentability, the reference must disclose each and every element of the claimed invention. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 U.S.P.Q. 781, 789 (Fed. Cir. 1983). Applicants respectfully submit that Bloom does not disclose each and every element of Claims 1-3, 5, 9-11, 13-18, 24-29, 31-33, 35, 37-38, and 42-52.

Claim 1 of the present application includes, among other elements, "a handheld computing device having means for reading the prescribed medication data and the patient data

and comparing the data to confirm a match between the medication data and patient data, the handheld computing device having a transmitter capable of transmitting the medication delivery instruction from the handheld computing device to the medical device wherein the medical device is adapted to deliver the medication to the patient according to the instructions." This limitation is not disclosed by Bloom.

Specifically, Bloom does not disclose, teach, or suggest the advantages of using a handheld device to read patient data and medication data and compare them to each other, or to transmit medication delivery instructions directly to the medical device delivering the medication. Rather, Bloom discloses an automated medication management system (300) that receives data from a bar code scanner (70,1812) and contains a control and management system (304) that performs the functions of data-checking and controlling a module (308) for preparation and delivery of medication. (Bloom, Col. 10, Lines 26-62; Col. 11, Lines 34-64; Fig. 3). Additionally, Bloom discloses a portable data entry terminal (824) that can scan bar codes and check information entered into the terminal (824) against information in a pharmaceutical database (805). (Bloom, Col. 27, Lines 20-55; Col. 30, Lines 25-67; Col. 31, Lines 1-24). Bloom differs from the system of Claim 1, because the portable terminal (824) of Bloom compares data read by the scanner to data already existing in a database. On the other hand, the handheld device of the system of Claim 1 reads patient data and medication data and compares them to each other at the handheld device. Also, Bloom does not disclose that the portable terminal (824) is capable of transmitting medication delivery instructions to a medical device. The Examiner has not pointed to any teaching, disclosure, or suggestion in Bloom of the above limitations, and Applicants respectfully submit that none exists. Thus, Bloom does not disclose or suggest each and every element of Claim 1, and Claim 1 is patentably distinct over Bloom.

Claims 2, 3, 5, 9-11, and 13-15 depend from Claim 1 and include all of the elements of Claim 1. Thus, for the reasons stated above with respect to Claim 1, Claims 2, 3, 5, 9-11, and 13-15 are patentably distinct over Bloom.

Claim 16 includes, among other elements, "a personal digital assistant having a bar code scanner thereon and a data transmitter thereon, the personal digital assistant configured to scan the first bar code label and the second bar code label and compare data from the scanned labels to confirm a match between the medication data and patient data, the personal digital assistant

transmitter capable of transmitting the predetermined set of pumping instructions from the personal digital assistant to the infusion pump wherein the pump is adapted to deliver the medication to the patient according to the instructions." Bloom does not disclose or suggest the use of pumping instructions for medication delivery in connection with the bar code reader. Further, Bloom does not disclose, teach, or suggest the advantages of using a personal digital assistant to read patient data and medication data and compare and match them to each other, or to transmit pumping instructions directly to an infusion pump delivering the medication. Rather, Bloom discloses an automated medication management system (300) that receives data from a bar code scanner (70,1812) and contains a control and management system (304) that performs the functions of data-checking and controlling a module (308) for preparation and delivery of medication. (Bloom, Col. 10, Lines 26-62; Col. 11, Lines 34-64; Fig. 3).

Additionally, Bloom discloses a portable data entry terminal (824) that can scan bar codes and check information entered into the terminal (824) against information in a pharmaceutical database (805). (Bloom, Col. 27, Lines 20-55; Col. 30, Lines 25-67; Col. 31, Lines 1-24). Bloom differs from the system of Claim 16, because the portable terminal (824) of Bloom compares data read by the scanner to data already existing in a database. On the other hand, the personal digital assistant of the system of Claim 16 reads patient data and medication data and compares them to each other at the personal digital assistant. Also, Bloom does not disclose that the portable terminal (824) is capable of transmitting pumping instructions to an infusion pump. The Examiner has not pointed to any teaching, disclosure, or suggestion in Bloom of the above limitations, and Applicants respectfully submit that none exists. Thus, Bloom does not disclose or suggest each and every element of Claim 16, and Claim 16 is patentably distinct over Bloom.

Claims 17, 18, and 24-28 depend from Claim 16 and include all of the elements of Claim 16. Thus, for the reasons stated above with respect to Claim 16, Claims 17, 18, and 24-28 are patentably distinct over Bloom.

Claim 29 includes, among other elements, "a handheld computing device with: means for reading the prescribed medication data, the medication delivery instruction, and the patient data . . . wherein the handheld computing device reads and stores the prescribed medication data and the patient data, performs a matching check between the prescribed medication data and the

patient data to confirm a match, and communicates the medication delivery instruction to the electronic medication delivery device to deliver the medication to the patient." As discussed above with respect to Claim 1, Bloom does not disclose, teach, or suggest the advantages of using a handheld device to read and perform a matching check between patient data and medication data, or to communicate medication delivery instructions directly to the medical device delivering the medication. Rather, Bloom discloses an automated medication management system (300) that receives data from a bar code scanner (70,1812) and contains a control and management system (304) that performs the functions of data-checking and controlling a module (308) for preparation and delivery of medication. (Bloom, Col. 10, Lines 26-62; Col. 11, Lines 34-64; Fig. 3).

Additionally, Bloom discloses a portable data entry terminal (824) that can scan bar codes and check information entered into the terminal (824) against information in a pharmaceutical database (805). (Bloom, Col. 27, Lines 20-55; Col. 30, Lines 25-67; Col. 31, Lines 1-24). Bloom differs from the system of Claim 29, because the portable terminal (824) of Bloom compares data read by the scanner to data already existing in a database. On the other hand, the handheld device of the system of Claim 29 reads patient data and medication data and compares them to each other at the handheld device. Also, Bloom does not disclose that the portable terminal (824) is capable of communicating medication delivery instructions to a medical device. The Examiner has not pointed to any teaching, disclosure, or suggestion in Bloom of the above limitations, and Applicants respectfully submit that none exists. Thus, Bloom does not disclose or suggest each and every element of Claim 29, and Claim 29 is patentably distinct over Bloom.

Claims 31-33, 35, 37-38, and 42-49 depend from Claim 29 and include all of the elements of Claim 29. Thus, for the reasons stated above with respect to Claim 29, Claims 31-33, 35, 37-38, and 42-49 are patentably distinct over Bloom.

Claim 50 includes, among other elements, "a handheld computing device with: means for reading the prescribed medication data, medication delivery instruction, and patient data . . . wherein the handheld computing device reads the prescribed medication data and the patient data, performs a matching check to confirm a match between the prescribed medication data and the patient data, and communicates the instruction of delivering the prescribed medication to the

medication delivery device to deliver the medication to the patient." As discussed above with respect to Claim 1, Bloom does not disclose, teach, or suggest the advantages of using a handheld device to read and perform a matching check between patient data and medication data, or to communicate medication delivery instructions directly to the medical device delivering the medication. Rather, Bloom discloses an automated medication management system (300) that receives data from a bar code scanner (70,1812) and contains a control and management system (304) that performs the functions of data-checking and controlling a module (308) for preparation and delivery of medication. (Bloom, Col. 10, Lines 26-62; Col. 11, Lines 34-64; Fig. 3).

Additionally, Bloom discloses a portable data entry terminal (824) that can scan bar codes and check information entered into the terminal (824) against information in a pharmaceutical database (805). (Bloom, Col. 27, Lines 20-55; Col. 30, Lines 25-67; Col. 31, Lines 1-24). Bloom differs from the system of Claim 50, because the portable terminal (824) of Bloom compares data read by the scanner to data already existing in a database. On the other hand, the handheld device of the system of Claim 50 reads patient data and medication data and compares them to each other at the handheld device. Also, Bloom does not disclose that the portable terminal (824) is capable of communicating medication delivery instructions to a medical device. The Examiner has not pointed to any teaching, disclosure, or suggestion in Bloom of the above limitations, and Applicants respectfully submit that none exists. Thus, Bloom does not disclose or suggest each and every element of Claim 50, and Claim 50 is patentably distinct over Bloom.

Claims 51 and 52 depend from Claim 50 and include all of the elements of Claim 50. Thus, for the reasons stated above with respect to Claim 50, Claims 51 and 52 are patentably distinct over Bloom.

2. Rejections Over Palti

In paragraph 1 of the Office Action, the Examiner rejected Claims 1-3, 5, 9-11, 13-18, 24-29, 31-33, 35, 37-38, and 42-52 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,700,998 to Palti ("Palti"). Applicants respectfully traverse this rejection. Applicants

respectfully submit that Palti does not disclose each and every element of Claims 1-3, 5, 9-11, 13-18, 24-29, 31-33, 35, 37-38, and 42-52.

Claim 1 of the present application includes, among other elements, "a handheld computing device having means for reading the prescribed medication data and the patient data and comparing the data to confirm a match between the medication data and patient data, the handheld computing device having a transmitter capable of transmitting the medication delivery instruction from the handheld computing device to the medical device wherein the medical device is adapted to deliver the medication to the patient according to the instructions." This limitation is not disclosed by Palti. Specifically, Palti does not disclose, teach, or suggest the advantages of using a handheld device to read patient data and medication data and compare them to each other, or to transmit medication delivery instructions directly to the medical device delivering the medication. Palti discloses a method of coding drug pills which includes the use of a portable bar code reader to scan bar codes on a patient and on a particular drug. (Palti, Col. 7, Lines 9-63). Palti also teaches a control system, with a processor, connected to the code reader. (Palti, Col. 7, Lines 9-67). The control system of Palti downloads a file containing patient and medical data from another computer and compares the information read from the bar codes to the information in that file. (Palti, Col. 7, Lines 9-67). Palti differs from the system of Claim 1, because the control system of Palti compares data read by the scanner to data already existing in a file. On the other hand, the handheld device of the system of Claim 1 reads patient data and medication data and compares them to each other at the handheld device. Also, Palti does not disclose that the portable terminal (824) is capable of transmitting medication delivery instructions to a medical device. Finally, although Palti discloses a "portable" computing device (Col. 7, Lines 28-31), it does not disclose a "handheld computing device" as in Claim 1. The Examiner has not pointed to any teaching, disclosure, or suggestion in Palti of the above limitations, and Applicants respectfully submit that none exists. Thus, Palti does not disclose or suggest each and every element of Claim 1, and Claim 1 is patentably distinct over Palti.

Claims 2, 3, 5, 9-11, and 13-15 depend from Claim 1 and include all of the elements of Claim 1. Thus, for the reasons stated above with respect to Claim 1, Claims 2, 3, 5, 9-11, and 13-15 are patentably distinct over Palti.

Claim 16 includes, among other elements, "a personal digital assistant having a bar code scanner thereon and a data transmitter thereon, the personal digital assistant configured to scan the first bar code label and the second bar code label and compare data from the scanned labels to confirm a match between the medication data and patient data, the personal digital assistant transmitter capable of transmitting the predetermined set of pumping instructions from the personal digital assistant to the infusion pump wherein the pump is adapted to deliver the medication to the patient according to the instructions." Palti does not disclose or suggest the use of pumping instructions for medication delivery in connection with the bar code reader. Further, Palti does not disclose, teach, or suggest the advantages of using a personal digital assistant to read patient data and medication data and compare and match them to each other, or to transmit pumping instructions directly to an infusion pump delivering the medication. Palti discloses a method of coding drug pills which includes the use of a portable bar code reader to scan bar codes on a patient and on a particular drug. (Palti, Col. 7, Lines 9-63). Palti also teaches a control system, with a processor, connected to the code reader. (Palti, Col. 7, Lines 9-67). The control system of Palti downloads a file containing patient and medical data from another computer and compares the information read from the bar codes to the information in that file. (Palti, Col. 7, Lines 9-67). Palti differs from the system of Claim 16, because the control system of Palti compares data read by the scanner to data already existing in a file. On the other hand, the personal digital assistant of the system of Claim 16 reads patient data and medication data and compares them to each other at the personal digital assistant. Also, Bloom does not disclose that the portable terminal (824) is capable of transmitting pumping instructions to an infusion pump. Finally, although Palti discloses a "portable" computing device (Col. 7, Lines 28-31), it does not disclose a "personal digital assistant" as in Claim 16. The Examiner has not pointed to any teaching, disclosure, or suggestion in Palti of the above limitations, and Applicants respectfully submit that none exists. Thus, Palti does not disclose or suggest each and every element of Claim 16, and Claim 16 is patentably distinct over Palti.

Claims 17, 18, and 24-28 depend from Claim 16 and include all of the elements of Claim 16. Thus, for the reasons stated above with respect to Claim 16, Claims 17, 18, and 24-28 are patentably distinct over Palti.

Claim 29 includes, among other elements, "a handheld computing device with: means for reading the prescribed medication data, the medication delivery instruction, and the patient data . . . wherein the handheld computing device reads and stores the prescribed medication data and the patient data, performs a matching check between the prescribed medication data and the patient data to confirm a match, and communicates the medication delivery instruction to the electronic medication delivery device to deliver the medication to the patient." As discussed above with respect to Claim 1, Palti does not disclose, teach, or suggest the advantages of using a handheld device to read and perform a matching check between the patient data and medication data, or to read and communicate medication delivery instructions directly to the medical device delivering the medication. Palti discloses a method of coding drug pills which includes the use of a portable bar code reader to scan bar codes on a patient and on a particular drug. (Palti, Col. 7, Lines 9-63). Palti also teaches a control system, with a processor, connected to the code reader. (Palti, Col. 7, Lines 9-67). The control system of Palti downloads a file containing patient and medical data from another computer and compares the information read from the bar codes to the information in that file. (Palti, Col. 7, Lines 9-67). Palti differs from the system of Claim 29, because the control system of Palti compares data read by the scanner to data already existing in a file. On the other hand, the handheld device of the system of Claim 29 reads patient data and medication data and compares them to each other at the handheld device. Also, Palti does not disclose that the portable terminal (824) is capable of communicating medication delivery instructions to a medical device. Finally, although Palti discloses a "portable" computing device (Col. 7, Lines 28-31), it does not disclose a "handheld computing device" as in Claim 29. The Examiner has not pointed to any teaching, disclosure, or suggestion in Palti of the above limitations, and Applicants respectfully submit that none exists. Thus, Palti does not disclose or suggest each and every element of Claim 29, and Claim 29 is patentably distinct over Palti.

Claims 31-33, 35, 37-38, and 42-49 depend from Claim 29 and include all of the elements of Claim 29. Thus, for the reasons stated above with respect to Claim 29, Claims 31-33, 35, 37-38, and 42-49 are patentably distinct over Palti.

Claim 50 includes, among other elements, "a handheld computing device with: means for reading the prescribed medication data, medication delivery instruction, and patient data . . .

wherein the handheld computing device reads the prescribed medication data and the patient data, performs a matching check to confirm a match between the prescribed medication data and the patient data, and communicates the instruction of delivering the prescribed medication to the medication delivery device to deliver the medication to the patient." As discussed above with respect to Claim 1, Palti does not disclose, teach, or suggest the advantages of using a handheld device to read and perform a matching check between the patient data and medication data, or to communicate medication delivery instructions directly to the medical device delivering the medication. Palti discloses a method of coding drug pills which includes the use of a portable bar code reader to scan bar codes on a patient and on a particular drug. (Palti, Col. 7, Lines 9-63). Palti also teaches a control system, with a processor, connected to the code reader. (Palti, Col. 7, Lines 9-67). The control system of Palti downloads a file containing patient and medical data from another computer and compares the information read from the bar codes to the information in that file. (Palti, Col. 7, Lines 9-67). Palti differs from the system of Claim 50, because the control system of Palti compares data read by the scanner to data already existing in a file. On the other hand, the handheld device of the system of Claim 50 reads patient data and medication data and compares them to each other at the handheld device. Also, Palti does not disclose that the portable terminal (824) is capable of communicating medication delivery instructions to a medical device. Finally, although Palti discloses a "portable" computing device (Col. 7, Lines 28-31), it does not disclose a "handheld computing device" as in Claim 50. The Examiner has not pointed to any teaching, disclosure, or suggestion in Palti of the above limitations, and Applicants respectfully submit that none exists. Thus, Palti does not disclose or suggest each and every element of Claim 50, and Claim 50 is patentably distinct over Palti.

Claims 51 and 52 depend from Claim 50 and include all of the elements of Claim 50. Thus, for the reasons stated above with respect to Claim 50, Claims 51 and 52 are patentably distinct over Palti.

3. Rejections Over Chaco

In paragraph 1 of the Office Action, the Examiner rejected Claims 1-3, 5, 9-11, 13-18, 24-29, 31-33, 35, 37-38, and 42-52 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,465,082 to Chaco ("Chaco"). Applicants respectfully traverse this rejection. Applicants

respectfully submit that Chaco does not disclose each and every element of Claims 1-3, 5, 9-11, 13-18, 24-29, 31-33, 35, 37-38, and 42-52.

Claim 1 of the present application includes, among other elements, "a handheld computing device having means for reading the prescribed medication data and the patient data and comparing the data to confirm a match between the medication data and patient data, the handheld computing device having a transmitter capable of transmitting the medication delivery instruction from the handheld computing device to the medical device wherein the medical device is adapted to deliver the medication to the patient according to the instructions." This limitation is not disclosed by Chaco. Chaco discloses a computer system for ensuring that medical materials are provided to the correct patient by use of information gathered by scanning bar codes. (Chaco, Col. 18-20). The system of Chaco incorporates either a stationary patient station (210) or a portable reader (2310), each of which scans bar codes using a light pen (222,2328) and compares patient data or medication data to information stored on a patient memory card. (Chaco, Col. 18, Lines 45-67; Col. 19, Lines 1-2; Col. 20, Lines 16-28). However, Chaco does not disclose, teach, or suggest the advantage of using a handheld device to compare scanned patient data to scanned medication data. Instead, the system disclosed in Chaco compares scanned patient data to patient data located on a patient memory card, and compares scanned medication data to medication data located on a patient memory card. (Chaco, Col. 18, Lines 45-67). Chaco also does not disclose, teach, or suggest the advantage of using a handheld device to transmit medication delivery instructions directly to the medical device delivering the medication. In fact, Chaco does not disclose or suggest that scanned or transmitted information may include medication delivery instructions, or that the disclosed system can be used with medical devices for medication delivery. The Examiner has not pointed to any teaching, disclosure, or suggestion in Chaco of the above limitations, and Applicants respectfully submit that none exists. Thus, Chaco does not disclose or suggest each and every element of Claim 1, and Claim 1 is patentably distinct over Chaco.

Claims 2, 3, 5, 9-11, and 13-15 depend from Claim 1 and include all of the elements of Claim 1. Thus, for the reasons stated above with respect to Claim 1, Claims 2, 3, 5, 9-11, and 13-15 are patentably distinct over Chaco.

Claim 16 includes, among other elements, "a personal digital assistant having a bar code scanner thereon and a data transmitter thereon, the personal digital assistant configured to scan the first bar code label and the second bar code label and compare data from the scanned labels to confirm a match between the medication data and patient data, the personal digital assistant transmitter capable of transmitting the predetermined set of pumping instructions from the personal digital assistant to the infusion pump wherein the pump is adapted to deliver the medication to the patient according to the instructions." Chaco does not disclose, teach, or suggest the advantage of using a handheld device to compare and match scanned patient data with scanned medication data. Instead, the system disclosed in Chaco compares scanned patient data to patient data located on a patient memory card, and compares scanned medication data to medication data located on a patient memory card. (Chaco, Col. 18, Lines 45-67). Chaco also does not disclose, teach, or suggest the advantage of using a handheld device to transmit pumping instructions directly to the infusion pump delivering the medication. In fact, Chaco does not disclose or suggest that scanned or transmitted information may include pumping instructions, or that the disclosed system can be used with infusion pumps for medication delivery. Finally, Chaco does not disclose or suggest that the bar code reader may be part of a "personal digital assistant" as in Claim 16. The Examiner has not pointed to any teaching, disclosure, or suggestion in Chaco of the above limitations, and Applicants respectfully submit that none exists. Thus, Chaco does not disclose or suggest each and every element of Claim 16, and Claim 16 is patentably distinct over Chaco.

Claims 17, 18, and 24-28 depend from Claim 16 and include all of the elements of Claim 16. Thus, for the reasons stated above with respect to Claim 16, Claims 17, 18, and 24-28 are patentably distinct over Chaco.

Claim 29 includes, among other elements, "a handheld computing device with: means for reading the prescribed medication data, the medication delivery instruction, and the patient data . . . wherein the handheld computing device reads and stores the prescribed medication data and the patient data, performs a matching check between the prescribed medication data and the patient data to confirm a match, and communicates the medication delivery instruction to the electronic medication delivery device to deliver the medication to the patient." As discussed above with respect to Claim 1, Chaco does not disclose, teach, or suggest the advantage of using

a handheld device to compare scanned patient data to scanned medication data. Instead, the system disclosed in Chaco compares scanned patient data to patient data located on a patient memory card, and compares scanned medication data to medication data located on a patient memory card. (Chaco, Col. 18, Lines 45-67). Chaco also does not disclose, teach, or suggest the advantage of using a handheld device to communicate medication delivery instructions directly to the medical device delivering the medication. In fact, Chaco does not disclose or suggest that scanned or transmitted information may include medication delivery instructions, or that the disclosed system can be used with medical devices for medication delivery. The Examiner has not pointed to any teaching, disclosure, or suggestion in Chaco of the above limitations, and Applicants respectfully submit that none exists. Thus, Chaco does not disclose or suggest each and every element of Claim 29, and Claim 29 is patentably distinct over Chaco.

Claims 31-33, 35, 37-38, and 42-49 depend from Claim 29 and include all of the elements of Claim 29. Thus, for the reasons stated above with respect to Claim 29, Claims 31-33, 35, 37-38, and 42-49 are patentably distinct over Chaco.

Claim 50 includes, among other elements, "a handheld computing device with: means for reading the prescribed medication data, medication delivery instruction, and patient data . . . wherein the handheld computing device reads the prescribed medication data and the patient data, performs a matching check to confirm a match between the prescribed medication data and the patient data, and communicates the instruction of delivering the prescribed medication to the medication delivery device to deliver the medication to the patient." As discussed above with respect to Claim 1, Chaco does not disclose, teach, or suggest the advantage of using a handheld device to compare scanned patient data to scanned medication data. Instead, the system disclosed in Chaco compares scanned patient data to patient data located on a patient memory card, and compares scanned medication data to medication data located on a patient memory card. (Chaco, Col. 18, Lines 45-67). Chaco also does not disclose, teach, or suggest the advantage of using a handheld device to communicate medication delivery instructions directly to the medical device delivering the medication. In fact, Chaco does not disclose or suggest that scanned or transmitted information may include medication delivery instructions, or that the disclosed system can be used with medical devices for medication delivery. The Examiner has not pointed to any teaching, disclosure, or suggestion in Chaco of the above limitations, and

Applicants respectfully submit that none exists. Thus, Chaco does not disclose or suggest each and every element of Claim 50, and Claim 50 is patentably distinct over Chaco.

Claims 51 and 52 depend from Claim 50 and include all of the elements of Claim 50. Thus, for the reasons stated above with respect to Claim 50, Claims 51 and 52 are patentably distinct over Chaco.

C. Claim Rejections Under 35 U.S.C. § 103(a)

1. No Disclosure of All Elements

In paragraph 2 of the Office Action, the Examiner rejected Claims 4, 6-8, 12, 19-23, 34, 36, 39-41, and 53 under 35 U.S.C. § 103(a) as being obvious over Bloom, Palti, and Chaco, in view of U.S. Patent No. 6,021,392 to Lester *et al.* ("Lester"). Applicants respectfully traverse this rejection. Applicants submit that the disclosures, teachings, suggestions, and motivations found in Bloom, Palti, Chaco, and Lester, alone or in combination, cannot establish a *prima facie* case of obviousness with respect to Claims 4, 6-8, 12, 19-23, 34, 36, 39, 40-41, and 53.

The law is clear that "[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Applicants submit that the proposed combination of Bloom, Palti, Chaco, and Lester does not disclose, teach, or suggest all limitations of Claim 1, or of dependent Claims 4, 6-8, and 12. Specifically, Applicants submit that the cited prior art does not disclose, teach, or suggest the limitation, "a handheld computing device having means for reading the prescribed medication data and the patient data and comparing the data to confirm a match between the medication data and patient data, the handheld computing device having a transmitter capable of transmitting the medication delivery instruction from the handheld computing device to the medical device wherein the medical device is adapted to deliver the medication to the patient according to the instructions." As discussed above, Bloom, Palti, and Chaco do not disclose this limitation. Applicants respectfully submit that Lester also does not disclose, teach, or suggest this limitation.

Lester discloses a computer management system for managing distribution and inventory of drugs in a health care center, which uses a handheld drug information collection unit (45) that communicates information to an interface computer (199) by connection to a recharging cradle

(165). (Lester, Col. 7, Lines 36-54; Col. 14, Lines 25-40). However, Lester does not even discuss the use of medication delivery instructions in connection with a bar coding system, and Lester's primary concern is toward inventory management -- not prevention of errors by checking medication data against patient data. Consequently, Lester does not disclose, teach, or suggest the advantages of using a handheld device to compare patient data to medication data, or to transmit medication delivery instructions directly to the medical device delivering the medication. The Examiner has not pointed to any teaching, disclosure, or suggestion in Lester of the above limitation, and Applicants respectfully submit that none exists. Therefore, Bloom, Palti, Chaco, and Lester, alone or in combination, fail to disclose, teach, or suggest the above limitation of Claim 1. Claims 4, 6-8, and 12 depend from Claim 1 and include all of the elements of Claim 1. Thus, the cited references do not disclose, teach or suggest all the limitations of Claims 4, 6-8, and 12, and the proposed combination of references cannot form the proper basis for a *prima facie* case of obviousness with respect to Claims 4, 6-8, and 12.

Claim 16, and thus dependent Claims 19-23, include, among other elements, "a personal digital assistant having a bar code scanner thereon and a data transmitter thereon, the personal digital assistant configured to scan the first bar code label and the second bar code label and compare data from the scanned labels to confirm a match between the medication data and patient data, the personal digital assistant transmitter capable of transmitting the predetermined set of pumping instructions from the personal digital assistant to the infusion pump wherein the pump is adapted to deliver the medication to the patient according to the instructions." Applicants respectfully submit that the proposed combination of Bloom, Palti, Chaco, and Lester does not disclose, teach, or suggest this limitation.

As discussed above, Bloom, Palti, and Chaco do not disclose the above limitation of Claim 16. Applicants respectfully submit that Lester also does not disclose, teach, or suggest the above limitation. Lester does not even discuss the use of pumping instructions for an infusion pump in connection with a bar coding system, and Lester's primary concern is toward inventory management -- not prevention of errors by checking medication data against patient data. Consequently, Lester does not disclose, teach, or suggest the advantages of using a handheld device to compare and match patient data with medication data, or to transmit pumping instructions directly to an infusion pump delivering the medication. Finally, Lester does not

disclose the use of a "personal digital assistant" in connection with the bar coding system, as in Claim 16. The Examiner has not pointed to any teaching, disclosure, or suggestion in Lester of the above limitation, and Applicants respectfully submit that none exists. Therefore, Bloom, Palti, Chaco, and Lester, alone or in combination, fail to disclose, teach, or suggest the above limitation of Claim 16. Claims 19-23 depend from Claim 16 and include all of the elements of Claim 16. Thus, the cited references do not disclose, teach or suggest all the limitations of Claims 19-23, and the proposed combination of references cannot form the proper basis for a *prima facie* case of obviousness with respect to Claims 19-23.

Claim 29, and thus dependent Claims 34, 36, and 39-41, include, among other elements, "a handheld computing device with: means for reading the prescribed medication data, the medication delivery instruction, and the patient data . . . wherein the handheld computing device reads and stores the prescribed medication data and the patient data, performs a matching check between the prescribed medication data and the patient data to confirm a match, and communicates the medication delivery instruction to the electronic medication delivery device to deliver the medication to the patient." Applicants respectfully submit that the proposed combination of Bloom, Palti, Chaco, and Lester does not disclose, teach, or suggest this limitation.

As discussed above, Bloom, Palti, and Chaco do not disclose the above limitation of Claim 29. Applicants respectfully submit that Lester also does not disclose, teach, or suggest the above limitation. Lester does not even discuss the use of medication delivery instructions in connection with a bar coding system, and Lester's primary concern is toward inventory management -- not prevention of errors by checking medication data against patient data. Consequently, Lester does not disclose, teach, or suggest the advantages of using a handheld device to perform a matching check between the patient data and medication data, or to communicate medication delivery instructions directly to the medical device delivering the medication. The Examiner has not pointed to any teaching, disclosure, or suggestion in Lester of the above limitation, and Applicants respectfully submit that none exists. Therefore, Bloom, Palti, Chaco, and Lester, alone or in combination, fail to disclose, teach, or suggest the above limitation of Claim 29. Claims 34, 36, and 39-41 depend from Claim 29 and include all of the elements of Claim 29. Thus, the cited references do not disclose, teach or suggest all the

limitations of Claims 34, 36, and 39-41, and the proposed combination of references cannot form the proper basis for a *prima facie* case of obviousness with respect to Claims 34, 36, and 39-41.

Claim 50, and thus dependent Claim 53, include, among other elements, "a handheld computing device with: means for reading the prescribed medication data, medication delivery instruction, and patient data . . . wherein the handheld computing device reads the prescribed medication data and the patient data, performs a matching check to confirm a match between the prescribed medication data and the patient data, and communicates the instruction of delivering the prescribed medication to the medication delivery device to deliver the medication to the patient." Applicants respectfully submit that the proposed combination of Bloom, Palti, Chaco, and Lester does not disclose, teach, or suggest this limitation.

As discussed above, Bloom, Palti, and Chaco do not disclose the above limitation of Claim 50. Applicants respectfully submit that Lester also does not disclose, teach, or suggest the above limitation. Lester does not even discuss the use of medication delivery instructions in connection with a bar coding system, and Lester's primary concern is toward inventory management -- not prevention of errors by checking medication data against patient data. Consequently, Lester does not disclose, teach, or suggest the advantages of using a handheld device to perform a matching check between the patient data and medication data, or to communicate medication delivery instructions directly to the medical device delivering the medication. The Examiner has not pointed to any teaching, disclosure, or suggestion in Lester of the above limitation, and Applicants respectfully submit that none exists. Therefore, Bloom, Palti, Chaco, and Lester, alone or in combination, fail to disclose, teach, or suggest the above limitation of Claim 50. Claim 53 depends from Claim 50 and includes all of the elements of Claim 50. Thus, the cited references do not disclose, teach or suggest all the limitations of Claim 53, and the proposed combination of references cannot form the proper basis for a *prima facie* case of obviousness with respect to Claim 53.

2. No Suggestion or Motivation to Modify

The law is clear that there must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the modification suggested by Examiner. "[T]he mere fact that the prior art could be so modified

would not have made the modification obvious unless the prior art suggested the desirability of the modification." *In re Laskowski et. al.*, 10 U.S.P.Q. 2d 1397, 1398, (Fed. Cir. 1989), *citing In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). That motivation cannot come from the Applicants' invention itself. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). Thus, unless the references suggest the particular combination of elements themselves, they cannot render Applicants' invention obvious. *In re Mahurkar Patent Litigation*, 831 F.Supp. 1354, 1374, 28 U.S.P.Q.2d 1801, 1817 (N.D. Ill. 1993). The Examiner has pointed to no suggestion in any of the references to modify the teachings of Bloom, Palti, Chaco, or Lester to include the above-identified limitations of Claims 4, 6-8, 12, 19-23, 34, 36, 39-41, or 53. Applicants respectfully submit that no such motivation exists in the cited prior art references. Thus, the cited prior art cannot form the proper basis for a *prima facie* case of obviousness with respect to Claims 4, 6-8, 12, 19-23, 34, 36, 39-41, and 53.

D. Other Claims

As noted above, the Examiner has indicated in the Office Action Summary that Claims 30 and 54-57 are rejected, but has not articulated the grounds on which such claims are rejected. Applicants respectfully submit that Claims 30 and 54-57 are patentable over the cited prior art, and request allowance of the same.

Claim 30 depends from Claim 29 and includes all of the elements of Claim 29. Thus, for the reasons stated above with respect to Claim 29, Claim 30 is patentably distinct and nonobvious over the cited prior art.

Claims 54-57 depend from Claim 50 and include all of the elements of Claim 50. Thus, for the reasons stated above with respect to Claim 50, Claims 54-57 are patentably distinct and nonobvious over the cited prior art.

Applicants further note that the Examiner has not taken a position as to the patentability of Claim 58. Applicants respectfully submit that Claim 58 is patentable over the cited prior art, and request allowance of the same. Claim 58 depends from Claim 50 and includes all of the elements of Claim 50. Thus, for the reasons stated above with respect to Claim 50, Claim 58 is patentably distinct and nonobvious over the cited prior art.

E. Conclusion

In view of the foregoing, Applicants respectfully request reconsideration and allowance of Claims 1-58 in the present Application. Applicants submit that the Application is in condition for allowance and respectfully request an early notice of the same.

Respectfully submitted,

Date: July 9, 2004

By: _____

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Natalie L. Kurowski/202492.1

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANTS PTO-1449	Attorney Docket No.: EIS-5799 (1417G P 570) Application No. 10/043,891 Applicants: James Martucci et al. Filing Date: January 11, 2002 Art Unit: 3763

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name
	Re. 35,743	03/17/98	Pearson

FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Country	Trans.
	2266641	10/31/75	France	Abstract Only - see attached Abstract
	WO 8400493 A2	02/16/84	WIPO	Abstract Only - see attached Abstract
	2555744 A1	05/31/85	France	Abstract Only - see attached Abstract
	0233115 A1	08/19/87	EPO	Abstract Only - see attached Abstract
	3709857 A1	10/06/88	Germany	Abstract Only - see attached Abstract
	89/08264 A1	09/08/89	WIPO	Abstract Only - see attached Abstract
	3812584 A1	10/26/89	Germany	Abstract Only - see attached Abstract
	0384155 A2	08/29/90	EPO	Abstract Only - see attached Abstract
	DE 3922026 A1	01/17/91	Germany	Abstract Only - see attached Abstract
	WO 9321978 A1	11/11/93	WIPO	Abstract Only - see attached Abstract
	0633035 A1	01/11/95	EPO	Abstract Only - see attached Abstract
	DE 4339154 A1	05/18/95	Germany	Abstract Only - see attached Abstract

OTHER DOCUMENTS

Examiner Initial	

Examiner: _____ Date Considered: _____

Examiner: Initial if Citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANTS
PTO-1449

Attorney Docket No.: EIS-5799 (1417G P 570)
Application No. 10/043,891
Applicants: James Martucci et al.
Filing Date: January 11, 2002
Art Unit: 3763

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name
	None		

FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Country	Trans.
	155687	11.04.91	China	Yes
	9308204	16.09.93	Germany	Yes

OTHER DOCUMENTS

Examiner Initial	
	None

Examiner: _____ Date Considered: _____

Examiner: Initial if Citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Supplemental Information Disclosure Statement
PTO-1449

Abstract FR 2266641 A

The container comprises an upper compartment (1) with a clip on lid. A screw thread (16) is formed on the base. A magnetic strip (15) is fixed in the hollow (15) in the centre of the thread. The magnetic strip is used to carry information. A second, lower compartment (2) has a similar strip (25). The compartments are held together by a piece (3) comprising a screw (30) and a cover (31) for the lower compartment. The diameters of the components are the same. In one form the height of the combined lower compartment and connecting piece is the same as that of the upper compartment, simplifying handling.

Supplemental Information Disclosure Statement
PTO-1449

Abstract WO 8400493 A2 (DE 3227518 A)

The programmable electronic circuit controls an analgesic infusion pump according to the pain felt by the patient. It is operated by the patient but has a built in safeguard against overdose. This is achieved by circuit elements which allow a higher, limited dose for a limited period, after which the dose is reduced to a lower constant level which, for a preset period can not be altered by the patient.

A programmable control unit comprises a circuit which controls and monitors the time and rate of flow and a second circuit which controls the rate at which the flow is reduced. A third circuit monitors the infusion intervals. A memory holds the maximum permitted flow data.

Supplemental Information Disclosure Statement
PTO-1449

Abstract FR 2555744 A1

A memory chip (P) has its rear face in a groove in the wall of a sample tube. At the rear face is a contact area which consists of a metalised layer (MA) which extends around the tube on its external wall and into the base of the groove. A tape (M) covers the groove and leaves a supplementary contact ring free to which contacts (C0,C1,C2) are made. One contact (C0) has access to the rear face of the chip.

The chip consists of an EPROM which allows it to be reused. It has protected access requiring identification procedures since it contains confidential information regarding the results of the analysis.

Supplemental Information Disclosure Statement
PTO-1449

Abstract EP 233115 A1

A perfusion system injecting liquid into a patient is remotely monitored by measuring the liquid flow, periodically transmitting a signal representing the flow along a data cable to a screen, and displaying the information on the screen with a unique code identifying the system.

Apparatus for carrying out the process is also claimed. The volumes of liquid injected and remaining are pref. calculated and also displayed.

Supplemental Information Disclosure Statement
PTO-1449

Abstract DE 3709857 A1

Process data or patient badly signals in the form of uniquely addressable and coded signals are ent by radio to a receiver station. The signals can be coded using logic modules according to customer needs. This applies to both directions of transmission. Sync. sgnals regulate the call-up of data/signals for transmission.

The transceiving units may operate on different frequencies so that the transmitters sending at the same time do not interfere with one another with the help of a second transceiving system not only can data call be regulated but also process information can be sent from the central station to the machinery/person and there converted to a change in a process parameter.

Supplemental Information Disclosure Statement
PTO-1449

Abstract WO 8908264 A1

An automatic analysis of blood or of its constituents in a test tube is based on a attaching to the latter an electronic code carrier in which the data for the patient and for the sample are stored. The set is inserted in an analyzer which supplies a complete print-out for the data for patient and analysis.

A test tube (2) made of transparent plastic material, has a stopper (1) at one end and encloses a separating element (6) which is driven by centrifugal force towards the bottom (18). A plastic cap (30) is attached by a snap fit (42,44) to the bottom; it contains an electronic code carrier (3), made of polycarbonate, with data for the patient stored in the memory of an integrated circuit. The analyzer is controlled by the controlled by the stored data to process the sample and can furnish a print-out or the read of the personal computer can be used to display all the data on a screen.

Supplemental Information Disclosure Statement
PTO-1449

Abstract DE 3812584 A (EP 337924A)

The biofeedback device uses at least one sensor (1..3) for monitoring a given biological parameter. The parameter values are compared with reference values applied from a data memory, with the results of these comparisons fed to a control unit eg a microcomputer for a therapy device.

The latter has a pump (17,18) coupled to a medicament reservoir (19,20) operated by the control unit for intravenous, intra arterial, oral or intra liminal dosing of the medicament, the resulting response being monitored by the sensor (1..3). Pref. each peristaltic pump (17,18) has a respective reservoir (19,20) holding a medicament with a synergistic or antagonistic effect.

Supplemental Information Disclosure Statement
PTO-1449

Abstract EP 0384155 A2

The control unit (13) of an infusion pump and syringe (11) features duplicated CPUs (14,14a), working memories (15, 15a), read-only memories (16,16a) and write/read application memories (17,17a) with emergency power supply batteries (18,18a).

The unit is programmed through an interface (20) from a keyboard (28) with a special key (28a) for verification of correct data transmission and storage, enabling the user to compare the two displays (19,27). The application is formed by an interpreter integrated into the read-only memories (16,16a).

Supplemental Information Disclosure Statement
PTO-1449

Abstract DE 3922026 A1

A human health measurement and evaluation device has at least one sensor for a physiological parameter and a display for the measured value. Several physiological parameter measurement sensors (16,17,19-22) can be connected.

There is a memory device for storing measurement values or sequences of values and a pattern recognition device for detecting sequences and/or combination of measurement values and/or sequence combinations. An associated pattern evaluation device feeds diagnostic signals corresp. to the identified patterns to the display (11,12,14).

Supplemental Information Disclosure Statement
PTO-1449

Abstract WO 9321978 A1

The assembly comprises a pump unit (12) and a supply chamber (14) containing a medicinal substance. A programmable controller including a microprocessor, keyboard, and screen is provided to enable the medicine to be injected into the patient via an infusion tube at predetermined times.

The pump assembly and supply chamber may be removed from the controller, whilst still be controlled by it. Consequently a number of different pump units may be controlled by a single programmer, each being linked by a wire rather than being directly connected.

Supplemental Information Disclosure Statement
PTO-1449

Abstract EP 633035 A1 (DE 4320365 A)

Multi-point dosing system (1) delivers predetermined liq. streams from individual liq. sources (3) via separate lines (8). Each liq. is controlled by a flow influencing adjustment device (12) coupled to a programmable controller (4). Data fields (24) in the controller (4) describe dosing of at least the individual liq. streams which are on call from a control panel (5,50). The panel (5,50) has a data input connections (10) and a data reset control (6) connected to the controller (4). Selection switches (13) for individual liq. sources (3) and/or predetermined gps. (32) of liq. sources, are arranged as part of the data input connections (19), by which at least segments (16,30,31) of the data fields associated with the liq. sources (3) or gps. of liq. sources (32) can be displayed on the control panel (5,50); and the selection switches cause at least part of the data input connections (10) to operate in conjunction with the data fields associated with the selected liq. source (3) or sources.

Supplemental Information Disclosure Statement
PTO-1449

Abstract DE 4339154 A1

An anaesthetic protocol system has a number of vital parameters, such as blood pressure, heart rate, monitored (MDn) in real-time and fed over an interface (IF1.2) a database (DB1). A real-time characteristic indicating trends is established and stored in memory.

The memory operates on a ring cycle, such that the oldest cycle is overwritten by the latest. Snap-shots of sections of the characteristic can be obtained and entered into a second memory (DB2) for examination and use.